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2200-650 WEST GEORGIA ST.  
VANCOUVER, B.C.

Application No. : **2,382,442**  
Owner : ARADIGM CORPORATION  
Title : **PORE STRUCTURES FOR REDUCED PRESSURE  
AEROSOLIZATION**  
Classification : A61M 15/00 (2006.01)  
Your File No. : **48990,150**  
Examiner : Kristian Ewen, M.A.Sc.

YOU ARE HEREBY NOTIFIED OF A REQUISITION BY THE EXAMINER IN ACCORDANCE WITH SUBSECTION 30(2) OF THE *PATENT RULES*. IN ORDER TO AVOID ABANDONMENT UNDER PARAGRAPH 73(1)(A) OF THE *PATENT ACT*, A WRITTEN REPLY MUST BE RECEIVED WITHIN 6 MONTHS AFTER THE ABOVE DATE.

This application has been examined taking into account the:

Description, as originally filed;  
Claims, as originally filed; and  
Drawings, as originally filed.

This application has been examined taking into account applicant's correspondence on prior art received in this office on August 24, 2005.

The number of claims in this application is 18.

The examiner has identified the following defects in the application:

The claims are directed to a plurality of alleged inventions as follows:

**Group A** - Claims 1 to 10 are directed to a nozzle comprising a sheet of flexible membrane having pores; and  
**Group B** - Claims 11 to 18 are directed to a container comprising a sheet of flexible membrane material having pores; and container walls collapsible under application of force.

The claims must be limited to one invention only as set out in section 36 of the *Patent Act*.

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In view of the above, a search of the prior art and examination have been limited to the subject matter in claims 1 to 10.

The search of the prior art has revealed the following:

Reference Applied:

United States Patents

|                        |               |              |                     |
|------------------------|---------------|--------------|---------------------|
| US 5 497 763 $\square$ | 12 March 1996 | US128/200.14 | Lloyd et al. ('763) |
|------------------------|---------------|--------------|---------------------|

Reference of Interest:

Canadian Patent Application

|              |            |            |                     |
|--------------|------------|------------|---------------------|
| CA 2 203 257 | 9 May 1996 | A61M 15/00 | Lloyd et al. ('257) |
|--------------|------------|------------|---------------------|

$\square$  citation stemming from a foreign search report

Lloyd et al. ('763) disclose a nozzle for aerosolizing a flowable liquid formulation for delivery to a patient, comprising: a sheet (3) of flexible membrane material having an entrance side to which said formulation is applied under a pressure, an exit side (17, 18) from which aerosol is released, and a nozzle area, which nozzle area has a plurality of pores therein through which said formulation is extruded, each of said pores having an entrance aperture and an exit aperture having a pore entrance aperture size and a pore exit aperture size, wherein the ratio of pore entrance aperture size to pore exit aperture size is at least 10:1. (cf. col 12, lines 33 to 35; col. 14, lines 11 to 19 and col 14, lines 23-36)

Lloyd et al. ('257) disclose a device for aerosolizing a flowable liquid formulation for delivery to a patient, comprising a sheet of flexible membrane material having an entrance side to which said formulation is applied under a pressure, an exit side from which aerosol is released, and a nozzle area, which nozzle area has a plurality of pores therein through which said formulation is extruded. The membrane includes pores having a diameter in the range of about 0.25 micron to about 6 microns and a pore density in the range of  $1 \times 10^4$  to about  $1 \times 10^8$  pores per square centimetre. The porous membrane thickness is varied from 10 to 200 microns.

Claims 1 to 10 do not comply with paragraph 28.2(1)(b) of the *Patent Act*. Lloyd et al. ('763) disclosed the claimed subject matter before the claim date.

The following formalities are also noted:

Claims 1 to 9, 11 and 15 are indefinite and do not comply with subsection 27(4) of the *Patent Act*. The inclusion of "about" causes ambiguity.

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A statement in an application, such as found on page 29, lines 32 and 33 which incorporates by reference any other document, does not comply with subsection 81(1) of the *Patent Rules*.

The applicant is requested to submit replacement pages compliant with subsection 68(1) and section 82 of the *Patent Rules*. Figures 1 and 3 to 5 are unclear and not reproducible. The applicant must submit replacement drawings clearly illustrating the alleged device.

In view of the foregoing defects, the applicant is requisitioned, under subsection 30(2) of the *Patent Rules*, to amend the application in order to comply with the *Patent Act* and the *Patent Rules* or to provide arguments as to why the application does comply.

Kristian Ewen, M.A.Sc.

Patent Examiner - Mechanical Division

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